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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MASASHI OKAMOTO, TATSUO KAMATA,
YUJI IZUMIZAWA, and ATSUSHI MURAKAMI

Appeal 2010-002788
Application 10/522,045
Technology Center 1600

Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and
STEPHEN WALSH, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This appeal under 35 U.S.C. § 134 involves claims 1, 4-12, and 14-26, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

The claims are directed to a method of collecting a microorganism or a cell from a liquid sample. Claim 1 is representative and is reproduced in "APPENDIX A" of Appellants' Brief (App. Br. 10).

The rejections presented by the Examiner follow:

1. Claims 1, 4-8, 10-12, 14, 25, and 26 stand rejected under 35 U.S.C § 103(a) as unpatentable over the combination of Wardlaw[2], Lyman[3], and Tsuchiya[4].

2. Claims 9 and 16-24 stand rejected under 35 U.S.C § 103(a) as unpatentable over the combination of Wardlaw, Lyman, Tsuchiya, and Britschgi[5].

3. Claim 15 stands rejected under 35 U.S.C § 103(a) as unpatentable over the combination of Wardlaw, Lyman, Tsuchiya, and Krupey[6].

We affirm. However, because our rationale differs from the Examiner's, we designate the affirmance a new ground of rejection.

ISSUE

Does the preponderance of evidence on this record support a conclusion of obviousness?

FINDINGS OF FACT

FF 1. "Sato teaches a method of collecting a virus from a liquid sample using particles[, such as hydrogel particles] capable of being bound by virus[ ]" (Ans. 3).

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[2] Wardlaw, US 2001/0033808 A1, published October 25, 2001.
[3] Lyman et al., US 4,683,058, issued July 28, 1987.
[4] Tsuchiya, US 5,747,277, issued May 5, 1998.
[5] Britschgi et al., US 5,726,021, issued March 10, 1998.
[6] Krupey et al., US 5,658,779, issued August 19, 1997.

FF 2. Sato teaches "particles capable of being bound by viruses . . . having either a cationic group or an anionic group or both at their surfaces" (Sato 1: ¶ [0009]).

FF 3. "The anionic group in . . . [Sato's particles] may include a carboxyl group . . . . These *anionic groups may be present in the state they have formed salts*" (Sato 4: ¶ [0065] (emphasis added)).

FF 4. Sato's "carboxyl-containing particles may include polymer or copolymer particles of a carboxyl group-containing monomer", such as "*acrylic acid* [and] methacrylic acid" (Sato 4: ¶ [0069] (emphasis added)).

FF 5. "Wardlaw teaches a method that uses hydrogels for collecting microorganisms that are present in a liquid sample" (Ans. 5).

FF 6. Wardlaw teaches that suitable hydrogels include "*poly(acrylic acid) [in Na^+form]*" and "poly(methacrylic acid) [in Na^+form]" (Wardlaw 3: ¶ [0025] (emphasis added, alteration original))

FF 7. Appellants disclose that their "water-absorbing resin is not particularly limited" and that "[s]pecific examples of the water-absorbing resin include . . . crosslinking substances of polyacrylate polymer, crosslinking substance of polymethacrylate polymer . . . [wherein] [s]pecific examples of polyacrylate include *sodium polyacrylate*" (Spec. 4: 33 - 5: 13 (emphasis added)).

FF 8. Sato's "virus-binding particles . . . [are] *desirably* added to a sample in the form of a virus-separating reagent prepared by the virus-binding particles in a medium such as saline" (Sato 7: ¶ [0097] (emphasis added)).

FF 9. "Sato does not teach that the water absorbing resin particles (i.e. hydrogels) absorb substantially all of the liquid in the liquid phase of the sample" (Ans. 4-5).

FF 10. Wardlaw teaches that "it is typically *desired* to use enough hydrogel so that essentially all of the water in the sample will be absorbed" (Ans. 5; *see also* Wardlaw 4: ¶ [0032] (Wardlaw suggests the use of a hydrogel that is not in its aqueous equilibrium state so that the hydrogel will absorb the aqueous phase of a sample placed into contact with the hydrogel).

FF 11. The Examiner finds that "in instances where there is enough hydrogel to absorb essentially all of the water in the sample, one would not have to separate the water absorbing particles from the liquid phase prior to the collecting step" (Ans. 5).

FF 12. "Sato does not teach a method wherein the collecting solution is contacted with the water absorbing particles without separating the water absorbing particles from the liquid phase" (Ans. 4-5).

FF 13. Wardlaw teaches that "[i]solation and concentration of formed constituents[, e.g., microbes, cells, etc.[7],] on the hydrogel surface . . . allows harvesting of specific formed constituents from the hydrogel surface for further analysis of the harvested constituents" (Wardlaw 2: ¶ [0012]).

FF 14. Sato teaches the use of a collecting solution, e.g., *a salt solution*, to disassociate virus from the particles (Ans. 4 (emphasis added)).

FF 15. Appellants disclose that their "collecting solution is not particularly limited, and may be, for example, water, distilled water, ion exchanged water, ultrapure water, *a buffer, or the like*" (Spec. 4: 13-15 (emphasis added)).

FF 16. Wardlaw teaches that:

> It will be appreciated that the examination of various types of cells or particulates using the centrifugation technique is time-

[7] Wardlaw 1: ¶ [0007].

> consuming and requires considerable skill on the part of the technician. This technique is also not precise due to the loss or destruction of sample components during centrifugation, and in the case of urinalysis, the imprecision of the decantation and re-suspension steps.

(Wardlaw 1: ¶ [0006]).

FF 17. Wardlaw teaches that:

> Formed constituents can also be separated from a biologic fluid sample by filtering. . . . Problems encountered with this technique include the cost of the various filters; the need to know the size of the target formed constituents; the plumbing required to force the sample to flow through the filter; and the potential of filter clogging.

(Wardlaw 1: ¶ [0007]).

FF 18. Sato teaches that ultracentrifugation is an example of a conventional method for separating viruses (Sato 1: ¶ [0006]).

FF 19. The Examiner relies on Lyman to teach a "filter tube . . . adapted to fit within the upper portion of a standard plastic centrifugation tube", wherein upon centrifugation of a sample in the centrifugation tube "permeable materials [are allowed to] pass through the filter and accumulate at the bottom of the centrifugation tube" (Ans. 6-7).

FF 20. The Examiner relies on Tsuchiya to teach that a person of ordinary skill in the art would know how to select "a filter with an appropriate pore size for detecting a particular microorganism" (Ans. 7).

FF 21. The Examiner finds that while Sato teaches that the collected virus can be used for PCR analysis, Sato is not limited to using the isolated virus in PCR analysis because Sato teaches that "'the viruses having been separated by the particles are used to make nucleic acid extraction,

examination, and diagnosis, in particular, examination and diagnosis involving nucleic acid amplification' (para 0019)" (*id.* at 15; *see also* Sato 12: claim 9 ("A method of detecting viruses comprising the steps of . . . subjecting the viruses bound to the particles, to an immunological assay"))

FF 22. Appellants do "not contest[ ] the relevance of Britschgi to claims 9 and 16-24 nor its suitability for combination with Sato, Lyman and Tsuchiya" (App. Br. 9).

FF 23. Appellants do "not contest[ ] the relevance of Krupey to claim 15 nor its suitability for combination with Sato, Lyman and Tsuchiya" (*id.*).

ANALYSIS

The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claim 1 is representative.

In summary, the forgoing findings of fact establish that Sato teaches a method of collecting virus from a liquid sample wherein the virus is bound to hydrogel particles (FF 1). Sato's hydrogel particles may be polymers of acrylic acid or a salt form thereof (FF 2-4). "Wardlaw teaches a method that uses hydrogels for collecting microorganisms that are present in a liquid sample" (FF 5). Poly(acrylic acid) in sodium form is a suitable hydrogel for use in Wardlaw's method (FF 6). Appellants disclose that their water-absorbing resin is "not particularly limited" and includes resins, such as "sodium polyacrylate" (FF 7). Accordingly, the combination of Sato and Wardlaw suggests a resin with in the scope of Appellants' claim 1.

Sato differs from Wardlaw and Appellants' claim 1 by suggesting a desire to use a hydrogel resin that is already in or near its aqueous equilibrium state, i.e., a hydrogel in a medium such as saline, prior to the addition of sample (FF 8). Accordingly, Sato does not teach that the water

absorbing resin particles absorb substantially all of the liquid in the liquid phase of the sample (FF 9). Wardlaw, however, provides an alternative to Sato's method. In particular, Wardlaw suggests the desire to use a hydrogel that is not in its aqueous equilibrium state (FF 10). Accordingly, Wardlaw teaches that "it is typically desired to use enough hydrogel so that essentially all of the water in the sample will be absorbed" (*id.*).

As the Examiner explains, using a hydrogel in the form suggested by Wardlaw "one would not have to separate the water absorbing particles from the liquid phase prior to the collecting step" because essentially all of the aqueous phase will be absorbed by the hydrogel (FF 11). Therefore, while Sato does not teach a method wherein a "collecting solution is contacted with the water absorbing particles without [first] separating the water absorbing particles from the liquid phase" (FF 12), by modifying Sato with Wardlaw, Sato's preliminary separation step that separates the hydrogel from the aqueous supernatant becomes unnecessary.

Sato and Wardlaw both suggest the removal of a component adhered to a hydrogel surface (FF 13-14). In particular, Sato teaches the use of a collecting solution such as a salt solution (FF 14). Appellants disclose that their collecting solution is "not particularly limited" and includes solutions such as water, buffer, or the like (FF 15). Accordingly, Sato teaches a collecting solution within the scope of Appellants' claim 1. There is no persuasive evidence and/or argument that Sato's collecting solution could not be used to collect a component, e.g., a virus, adhered to a hydrogel as taught by Wardlaw.

While Wardlaw teaches that constituents, such as cells or particulates, can be separated from a fluid by centrifugation and/or filtration, Wardlaw

suggests that these techniques can be problematic for various reasons (FF 16-17). Nevertheless, Sato teaches that ultracentrifugation is a conventional method for separating virus (FF 18). In this regard, the Examiner relies on Lyman and Tsuchiya as evidence that a centrifugation tube and filter that falls with in the scope of Appellants' claim 1 was known in the art prior to the date of Appellants' claimed invention (*see* FF 19-20).

In view of the foregoing analysis, we agree with the Examiner that one of ordinary skill in the art would have found it prima facie obvious to modify Sato to include hydrogels capable of absorbing essentially all of the water in a sample (*see, e.g.,* Ans. 13-14).

We also agree with the Examiner's finding that Sato is not limited to the isolation of virus for PCR analysis (FF 21). Therefore, we are not persuaded by Appellants' contentions regarding the use of Sato's method in the preparation of a sample for nucleic acid amplification, e.g., PCR. (App. Br. 5-7).

Appellants contend that "Sato teaches that their particles . . . bind[, or specifically bind] and thereby separate[ ] only the viruses for the purposes of examining and diagnosing the viruses . . . (paragraph [007])" (App. Br. 6; *see also id.* at 8 ("Sato specifically teaches that their particles capture only the viruses, and leads away from using the particles in a manner that would capture components other than viruses as taught by Wardlaw)). Appellants have not identified, and we do not find, a requirement in the cited paragraph of Sato that suggests that Sato's particles only bind and/or separate virus. The same is true of Appellants' citation of Sato's "paragraph [0020], [0023], and [0065]" (*id.*). Accordingly, we are not persuaded by Appellants' unsupported contentions.

For the foregoing reasons we are not persuaded by Appellants' unsupported contention that "[t]he use of hydrogel particles in amounts that would absorb essentially all of the liquid in the sample as taught by Wardlaw would in fact frustrate the purposes of Sato", because "the hydrogel particles would capture unwanted components that may adversely affect the amplification reaction of the viral gene, which is often very sensitive to the presence of other components as indicated by Sato" (App. Br. 7).

We agree with Appellants' contention that in Sato's method "the amount of the [hydrogel] particles is dependent upon the amount of viruses present in the sample" (App. Br. 8). However, the rejection presented for our review is the combination of, *inter alia*, Sato and Wardlaw. As discussed above, when Sato's method is modified with Wardlaw's alternative hydrogel form the focus is no longer on the relationship between the virus and hydrogel, as taught by Sato, but instead shifts to the relationship between the aqueous volume of the sample and the hydrogel as taught by Wardlaw. Accordingly, we are not persuaded by Appellants' contention regarding Sato's teaching of a relationship between virus and the hydrogel (App. Br. 7-8).

We are not persuaded by Appellants' contention that "Wardlaw leads away from the use of centrifugation and filters as taught by Lyman and Tsuchiya" (App. Br. 8). Appellants have failed to provide persuasive argument and/or evidence that the problems associated with centrifugation and filtration discussed in Wardlaw (FF 16-17) are applicable to the isolation of virus, which as Sato discloses, are conventionally isolated by ultracentrifugation (FF 18).

For the foregoing reasons we find no error in the combination of Sato, Wardlaw, Lyman, and Tsuchiya. Because Appellants do not contest the relevance of Britschgi or Krupey in combination of Sato, Wardlaw, Lyman, and Tsuchiya (FF 23-24) we affirm the rejections over Sato, Wardlaw, Lyman, and Tsuchiya in combination with either Britschgi or Krupey. Arguments not made are waived. *See* 37 C.F.R. § 41.37(c)(1)(vii).

CONCLUSION OF LAW

The preponderance of evidence on this record supports a conclusion of obviousness.

The rejection of claim 1 under 35 U.S.C § 103(a) as unpatentable over the combination of Sato, Wardlaw, Lyman, and Tsuchiya is affirmed. Claims 4-8, 10-12, 14, 25, and 26 fall together with claim 1.

The rejection of claims 9 and 16-24 under 35 U.S.C § 103(a) as unpatentable over the combination of Sato, Wardlaw, Lyman, Tsuchiya, and Britschgi is affirmed.

The rejection of claim 15 under 35 U.S.C § 103(a) as unpatentable over the combination of Sato, Wardlaw, Lyman, Tsuchiya, and Krupey is affirmed.

TIME PERIOD FOR RESPONSE

Because our rationale differs from that of the Examiner, we designate the affirmance as a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the Appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) Reopen prosecution. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner. . . .
> (2) Request rehearing. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

AFFIRMED; 37 C.F.R. § 41.50(b)

dm

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